

Remarks

This paper is filed in response to the Office Action mailed January 24, 2008, in which the Examiner advised that claims 7,9 and 15-24 are rejected. Applicants have herein amended claims 7, 9, 15, and 20, and Applicants respectfully request reconsideration of this application in light of the amendments and arguments presented herein.

Before responding to the rejections included in the Office Action, Applicants respectfully note that the claims have been amended herein to cancel non-elected subject matter previously contained therein.

I. Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 7, 9, and 15 through 24 are rejected under 35 U.S.C. § 112, first paragraph, ("Section 112, first paragraph") for allegedly failing to comply with the written description requirement. Without acquiescing to such rejection, and in order to speed allowance of the present application, Applicants have herein amended claims 7, 9, 15, and 20 such that they more specifically recite subject matter explicitly supported by the specification as filed. More specifically, Applicants have amended claims 7, 9, 15, and 20 to recite, in part, obtaining one or more plant parts from a plant of the genus Asimina are selected from one or more twig, unripe fruit, seed, bark and other bioactive plant part, or any combination thereof. Support for the claim amendments may be found, *inter alia*, at paragraphs [0013] and [0014] of the application as filed.

In light of such amendments, Applicants respectfully request withdrawal of the rejection under Section 112, first paragraph.

II. Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 7, 9, and 15 through 24 are rejected under 35 U.S.C. § 112, first paragraph, ("Section 112, second paragraph") as allegedly failing to particularly point out and distinctly claim the subject matter which Applicants regard to be the invention.

Without acquiescing to such rejection, and in order to speed allowance of the present application, Applicants have herein amended claims 7, 9, 15, and 20 according to the Examiner's suggestions. In light of such amendments, Applicants respectfully request withdrawal of the rejection under Section 112, second paragraph.

III. Rejection Under 35 U.S.C. § 103(a)

Claims 7, 9 and 15 through 24 are rejected in the Office Action under 35 U.S.C. § 103(a) ("Section 103") as allegedly being obvious in light of the combined teachings of U.S. patent 5,717,113 to McLaughlin et al. ("McLaughlin et al.") and the article entitled "Evaluation of the Pawpaw Tree, *Asimina Triloba* (Annonaceae), as a Commercial Source of the Pesticidal Annonaceous Acetogenins" by Ratnayake et al. ("Ratnayake et al."). Applicants respectfully traverse this rejection because the combined teachings of the cited references fail to establish the *prima facie* obviousness of the pending claims.

It is well settled that the PTO has the burden to establish a *prima facie* case of obviousness. To meet this burden, the PTO must set forth an explicit analysis supporting the rejection. M.P.E.P. § 2142 (8th ed., rev. 6). "[R]ejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *Id.* (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). In particular, "all words in a claim must be considered in judging the patentability of that claim against the prior art." M.P.E.P. § 2143.03 (8th ed., rev. 6) (quoting *In re Wilson*, 424 F.2d 1382 (CCPA 1970)). In addition, the suggested modification cannot render the prior art unsatisfactory for its intended purpose (M.P.E.P. § 2143.03 (8th ed., rev. 6) (citing *In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984))). In this instance, the combined teachings of the references fail to teach or even suggest all the limitations recited in the rejected claims, and efforts to modify the teachings of either reference to

arrive at the claimed subject matter are not in harmony with the intended purposes of the technologies taught therein.

Claim 7 recites a method for preparing a crude extract containing one or more acetogenin compound. As recited in the claim, the crude extract prepared by such method has specific characteristics. In particular, the crude extract is suitable for administration to a human subject, is standardized for zero percent moisture, and exhibits an LC₅₀ of 0.5 ppm in a BST. Yet, neither of the references teaches or suggests a method for producing a crude extract having any of these limitations.

As Applicants have previously pointed out, the Ratnayake et al. reference, provides an evaluation of the suitability of the pawpaw tree as a commercial source of *pesticidal* Annonaceous acetogenins. Though the reference indicates that Annonaceous acetogenins have been reported to possess antitumor activity, the teachings of Ratnayake et al. are entirely focused on the viability of using extracts from one representative of the Annonaceae family (the pawpaw tree) for pesticidal purposes, not human consumption. Moreover, the teachings found in the Ratnayake et al. reference do not expressly or inherently teach a method that includes standardizing a crude extract to zero percent moisture and an LC₅₀ of 0.5 ppm in a BST, and nothing taught by Ratnayake et al. would suggest or guide one of ordinary skill in the art to arrive at a method of producing crude extract having all the characteristics recited in claim 7.

Combining the teachings of McLaughlin et al. with the teachings of Ratnayake et al. does not remedy such shortcomings. The McLaughlin et al. document recognizes that Annonaceous acetogenins are often bioactive, even characterizing their activity as "potent" and potentially useful as cytotoxic agents that may be used as antitumor or antileukemic agents. However, the teachings of McLaughlin et al. focus on isolating specific acetogenins and acetogenin derivatives as possibly therapeutic drugs. The teachings of McLaughlin et al. are not concerned with crude extracts or methods of producing such extracts. Considered as a whole, the technology of McLaughlin et al.:

1) would lead one of ordinary skill in the art to pursue particular isolated or purified compounds; and 2) does not combine with the teachings of Ratnayake et al. in a manner that would motivate one of skill in the art to arrive at a method having the specific limitations of claim 7 or suggest that a crude extract suitable for human consumption could be achieved through such a method. Therefore, the combined teachings of McLaughlin et al. and Ratnayake et al. do not support the *prima facie* obviousness of claim 7, and the rejection of claim 7 under Section 103 should be withdrawn.

Applicants also note that modification of the technologies taught by Ratnayake et al. and McLaughlin et al. to arrive at the subject matter recited in claim 7 would not be in harmony with the intended purposes of the technologies taught therein. Again, McLaughlin et al. focuses on identification of individual compounds suitable for formulation in a pharmaceutical composition. By definition and regulatory requirement, pharmaceutical products are well defined, with the active ingredients in such products each identified and characterized. Attempting to redirect the teachings of McLaughlin et al. to arrive at a method of forming a crude extract would render the teachings of McLaughlin et al. inappropriate for the reference's intended purpose. Similarly, Ratnayake et al. is directed at identifying compositions suitable as pesticides, a purpose entirely different than that explicitly recited in the rejected claims. Applicants, therefore, respectfully emphasize that the combined teachings of Ratnayake et al. and McLaughlin et al. do not establish the *prima facie* obviousness of claim 7, and request that the rejection of claim 7 under Section 103 be withdrawn.

Like claim 7, claims 9 and 15 through 24 also recite methods for preparing a crude extract containing one or more acetogenin compound. As is true of claim 7, claim 9 recites a method for producing a crude extract suitable for human consumption. Moreover, each of claims 9 and 15 through 24 recited methods for producing crude extracts having specific moisture content and LC₅₀ characteristics in a BST. Therefore, for the same reasons as detailed with respect to claim 7, Applicants respectfully submit that the combined teachings for Ratnayake et al. and McLaughlin et al. do not establish

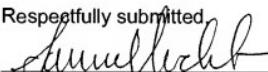
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the *prima facie* obviousness of claims 9 and 15 through 24, and Applicants respectfully request that the rejection of these claims under Section 103 be withdrawn.

CONCLUSION

Applicants respectfully assert that claims 7, 9, and 15 through 24 are patentably distinct from the cited references, and request that a timely Notice of Allowance be issued in this case. If there are any remaining issues preventing allowance of the pending claims that may be clarified by telephone, the Examiner is requested to call the undersigned.

Respectfully submitted,



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